

Dimension Vista® Intelligent Lab Systems with Software v.3.7 or v.3.8.1

Potential Unexpected Aliquot Contamination

Our records indicate that your laboratory has either the Dimension Vista® 500 Intelligent Lab System or Dimension Vista® 1500 Intelligent Lab System using v.3.7 or v.3.8.1 software versions.

Dimension Vista® Affected Products

Product	Siemens Material Number (SMN)
Dimension Vista 500 Intelligent Lab System	10284473
Dimension Vista 1500 Intelligent Lab System	10444801

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in the above table and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has identified an issue with Dimension Vista® software v.3.7 and v.3.8.1 that may result in aliquot well contamination.

If a test is cancelled by the operator while the instrument is aliquotting the sample, the Dimension Vista instrument may continue to deliver the cancelled sample or vial contents to the aliquot well(s). Future samples may be assigned to the same aliquot well(s) and become contaminated with the existing contents or overflow of the aliquot well may occur potentially contaminating a surrounding well(s).

This issue only occurs when an operator manually cancels a test(s) for calibration, quality control (QC) or patient sample while the instrument is in the process of aliquotting the sample.

Siemens is working to provide an updated software version to address this issue. Until the updated software version is installed, please refer to the "Actions to be Taken by the Customer" section in this letter.

Risk to Health

The potential exists to generate erroneously elevated or depressed patient results when this issue occurs, however, the likelihood of a clinically significant effect on patient results is remote. Clinical impact would be mitigated by correlation to clinical history and presentation as well as to other diagnostic laboratory testing, serial testing, and/or

concomitant imaging studies depending on the analyte. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

1. Whenever possible, order/test(s) for calibration, QC or patient samples should only be cancelled by the operator when the system has finished aliquotting the sample.

- Once the Sample Rack has been unloaded from the Dimension Vista the test(s) may be cancelled following normal procedure.

- For automation systems once the tube has been released back to the track the test(s) may be cancelled following normal procedure. This step not applicable to us. -JF

2. If the order/test(s) for calibration, QC or patient samples must be cancelled while the sample is onboard the system, please follow the instructions below:

a. From the Operation menu select "Pause".

b. When "System Paused" displays in the status area, the test(s) may be cancelled.

c. From the Operation menu select "Reset" to reset the Dimension Vista.

3. If order/test(s) for calibration, QC or patient samples were cancelled by the operator while the sample is onboard the system and the system was not paused:

a. From the Operations menu select "Stop". All in-progress tests will be aborted

b. From the Operations menu select "Shutdown"

c. The console menu is displayed. To restart system, select "Start Vista."

Note: try to avoid reaching this step. -JF

In addition, please perform the following:

- Review this letter with your Medical Director.
- Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.
- Return the completed Field Action Effectiveness Form to Siemens Healthcare Diagnostics as instructed in the last page of this letter.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens Technical Support Representative.

Dimension Vista is a trademark of Siemens Healthcare Diagnostics